K110746

TOMTEC IMAGING SYSTEMS

MAY 2 4 2011

March 23rd, 2011

Traditional 510(k) Summary

4D LV-Analysis 3.0

Owner's Name and Address
TomTec Imaging Systems GmbH
Edisonstrasse 6
D-85716 Unterschleissheim

Contact Person
Inge Scheidt
QM & RA Officer
Phone ++49-89-32175-515
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Common, Classification & Proprietary Names

Common Name: Various Image Analysis System Software

Classification Name: Programmable diagnostic computer

Proprietary Name(s): **4D LV-Analysis 3.0**

Predicate Devices:

Predicate Device 1	K071232	Image-Arena Platform 3.0; Research-Arena Platform 2.0; Echo-Com 3.x; Image-Com 3.x; 4D Cardio-View 2.x; 4D LV-Analysis 2.5x; 4D RV-Function 1.x; 4D MV Assessment 1.x; 4D LV-Function 2.x **Only 4D LV-Analysis 2.5x component,** TomTec Imaging Systems GmbH
Predicate Device 2	K090461	Image-Arena 4.0 and Image-Arena Applications **Only 2D Cardiac Performance Analysis 1.0 component**, TomTec Imaging Systems GmbH
Predicate Device 3	K082596	USWS-900A; UltraExtend Ultrasound WorkStation Package **Only ACP component** Toshiba America Medical Systems, Inc.

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Device Description

The 4D LV-Analysis© 3.0 software is a clinical application package for high performance PC platforms based on Microsoft Windows operating system standards. 4D LV-Analysis is software for the retrieval, reconstruction, rendering and analysis of digitized ultrasound B-mode images.
4D LV-Analysis is compatible with different TomTec Image-Arena™ platforms, their derivatives or any other platform that provides and supports the Generic CAP Interface. Platforms enhance the workflow by providing the database, import, export and other functionalities. All analyzed data and images will be transferred to the platform for reporting and statistical quantification purposes.
4D LV-Analysis is designed for 2- and 3-dimensional morphological and functional analyses of the left ventricle. Based on three dimensional datasets a semi-automatic 3D surface model finding algorithm supports the calculation of a 4D model that represents the cavity of the LV.
From that model, global as well as regional volumetric changes can be derived. By looking at the timing of regional contractions, dyssynchrony of a ventricle can be quantified and visualized. For visualization, parametric maps are used that indicate areas with a delayed contraction.
Thus 4D LV-Analysis improves the functional analysis of the LV and presentation of findings to cardiologists and electro-physiologists and visualizes the contraction pattern of the LV to assess dyssynchrony.

Intended Use

4D LV-Analysis is intended to retrieve, analyze, and store digital ultrasound images for computerized dynamic 3-dimensional image analysis.
4D LV-Analysis reads certain digital 3D/4D image file formats for reprocessing to a proprietary 3D/4D image file format for analysis. It is intended as a digital 4D ultrasound image processing tool for cardiology.

Indications for use

4D LV-Analysis 3.0 is intended as software for analysis of the left ventricle in heart failure patients.

Technological Characteristics Comparison

For detailed comparison of all software functionalities of the subject device and the predicate devices refer to Chapt.12: Substantial Equivalent discussion.

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Discussion according non-clinical performance data testing

Testing was performed according to internal company procedures. Software testing and validation were done at the module and system level according to written test protocols established before testing was conducted. Test results were reviewed by designated technical professionals before software proceeded to release. Please refer to Chapter 16: Software, Verification and Validation Documentation.

Discussion according clinical performance data testing

The overall product concept was clinically accepted and the clinical test results support the conclusion that the subject device is as safe as effective, and performs as well as the predicate devices. Please refer to Chapter 16: Software, Verification and Validation Documentation.

Test Conclusions of non-clinical and clinical performance data

Test results support the conclusion, that the subject device is as safe as effective, and performs as well as or better than the predicate devices. Please refer to Chapter 16: Software, Verification and Validation Documentation.

Munich, March 23rd, 2011

Inge Scheidt
QM & RA Officer

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Inge Scheidt
QM & RA Officer
TomTec Imaging Systems GmbH
Edisonstrasse 6
Unterschleissheim, Bavaria D-85716
GERMANY

MAY 2 4 2011

Re: K110746
Trade/Device Name: 4D LV-Analysis
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: II
Product Code: DQK and LLZ
Dated: March 16, 2011
Received: March 17, 2011

Dear Ms. Scheidt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110746

Device Name:

4D LV-Analysis 3.0

Indications for Use:

4D LV-Analysis 3.0 is intended as software for analysis of the left ventricle in heart failure patients.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Mary S Patel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110746